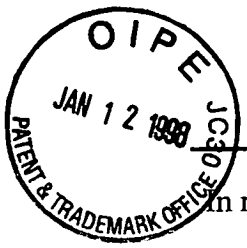
#20




**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re the application of: Edward L. Sinofsky

Serial No.: 08/411,581

Filed: March 29, 1995

For: INFRARED LASER CATHETER SYSTEM

Attorney Docket No.: **ROE-040C4**

Examiner: D. Shay

**Group Art Unit: 3311**

Assistant Commissioner for Patents
Washington, D.C. 20231

## DECLARATION UNDER RULE 132

Edward L. Sinofsky, Ph.D. declares as follows:

1. I am the inventor of the subject matter described and claimed in the above-captioned patent application. I hold a B.S. degree in Physics from the State University of New York, as well as M.S. and Ph.D. degrees in Optical Science from University of Arizona. Since receiving my Ph.D. degree in 1984, I have been employed in the field of fiber optic medical devices. A partial list of my publications and patents in the field of fiber optic medical devices is attached hereto.

2. I am presently the President and Chief Scientist of Rare Earth Medical, Inc. (REM), a company which I found in 1988 to exploit the minimally invasive applications of optical fibers for phototherapy. Prior to founding REM, I was employed by C.R. Bard, Inc.(BARD) as a research scientist in BARD's USCI division where I worked in the field of catheter systems and, in particular, on laser catheter systems.

3. I believe that my education, experience and knowledge gained from research and participation in clinical studies, qualifies me as someone skilled in medical applications of lasers.

4. The invention which is the subject matter of this application was conceived and reduced to practice by me at BARD. The rights in this application (and the three related patents that been cited during examination and overcome by the filing of terminal disclaimers) have been assigned by BARD to REM.

5. It is my understanding that the Examiner has rejected the pending claims in this application on obviousness grounds in light of certain references and "judicial notice that it was known in the art *"to employ low hydroxyl content fibers, since these were commercially available and known to transmit the desired wavelength at the time of the invention."*

6. I must disagree with this assertion. At the time of my invention, it was not general knowledge that low hydroxy ion content fibers could be used in medical applications to transmit infrared (IR) radiation at wavelengths between about 1.4 and 2.2 micrometers. To the contrary, the problem of transmitting such IR radiation in this wavelength range by fiber optics over distance of several meters had stymied me for a long period of time.

7. Specifically, at the time my invention was made, I was seeking to develop lasers for medical applications and that the existing laser sources were not well suited for this purpose. Although carbon dioxide ($CO_2$) lasers had been used for surgical purposes, such lasers generated output energy with a wavelength on the order of 10 micrometers. Energy in this wavelength regime was highly absorbed in water and blood. In addition, the available fiber optic systems for delivery of $CO_2$ laser radiation were unacceptable (due to toxicity, water solubility and lack of flexibility). Excimer lasers were also known at the time of my invention, but there were no suitable fiber optic transmission media. Because excimer lasers generate extremely high peak power pulses of radiation, attempts to channel such power into an optical fiber typically resulted in destruction of the fiber itself.

8. Faced with the lack of suitable laser sources, I realized that mid infrared radiation was required and that such radiation would also need to be transmitted through small, flexible, non-toxic glass fibers. I first attempted to utilize a laser source known as a Neodymium: Yttrium-Aluminum-Garnet (Nd:YAG) lasers. This laser was one of a class of new laser materials known as "rare earth lasers." Unfortunately, the Nd:YAG laser produced radiation at a wavelength on the order of 1.06 microns. Although this radiation could be transmitted via an optical fiber, the wavelength penetrated too deeply into biological tissue to permit surgical tissue removal or repair without significant thermal damage to surrounding areas.

9. After additional experimentation, I concluded that other rare earth lasers operating in the wavelength range of about 1.4 - 2.2 micrometers could achieve biological tissue removal and/or tissue repair without the disadvantages of the shorter wavelength Nd:YAG laser source. In particular, I discovered that the substitution of holmium, erbium or thulium in YAG crystal matrices (or similar crystals) would achieve laser radiation in a desired wavelength range.

10. To achieve a practical laser surgical system, however, I also had to improve upon the transmission characteristics of silica fibers. At first, I was unable to locate any existing glass fibers that could transmit the required energy levels for the required distance, which was on the order of ten feet. Following further experimentation and research, I discovered that the attenuation of laser radiation in this wavelength range was greatly affected by the presence of hydroxyl ions in the glass fibers, and, ultimately, discovered that silica fibers with reduced hydroxyl ion contents were capable of delivering the desired energy levels for the required distances to achieve his laser surgical system.

11. The low hydroxyl ion content fibers which I used were not commercially available but rather were special ordered. The manufacturer sold these products to me with out any guarantee that they would be successful in transmitting radiation in the specified IR wavelength range.

I hereby declare that all statements made herein of my own knowledge are true, and that all statements made on information and belief are believed to be true; and further that these statements were made with knowledge that willful false statements and the like are punishable by fine or imprisonment, or both, under Section 101 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application, or any patent issuing thereon.

Date 12/12/97 By: Edward L. Sinofsky Ph.D.
Edward L. Sinofsky, Ph.D.

## List of Dr. Sinofsky's US Patents

US Patent 5,643,253 issued July 1, 1997
"Phototherapy Apparatus with Integral Stopper Device"

US Patent 5,637,877 issued June 10, 1997
"Ultraviolet Sterilization of Instrument Lumens"

US Patent 5,632,767 issued May 27, 1997
"Loop Diffusers for Diffusion of Optical Radiation"

US Patent 5,569,239 issued October 29, 1996
"Photoreactive Suturing of Biological Materials"

US Patent 5,540,677 issued July 30, 1996
"Endoscopic Systems for Photoreactive Suturing of Biological Materials"

US Patent 5,363,387 issued November 8, 1994
"Variable Pulsewidth Lasers"

US Patent 5,261,904 issued October 19, 1993
"Laser Catheter Having Diffraction Grating for Beam Shaping"

US Patent 5,254,112 issued October 19, 1993
"Device for use in Laser Angioplasty"

US Patent 5,207,670 issued May 4, 1993
"Photoreactive Suturing of Biological Materials"

US Patent 5,207,669 issued May 4, 1993
"Optical Fiber Diffusion Tip for Uniform Illumination"

US Patent 5,196,004 issued March 23, 1993
"Infrared Laser Catheter System"

US Patent 5,135,001 issued August 4, 1992
"Ultrasound Sheath for Medical Diagnostic Instruments"

US Patent 5,123,421 issued June 23, 1992
"Liquid Activated Steerable Catheter Guidewire"

US Patent 5,100,429 issued March 31, 1992
"Endovascular Stent and Delivery System"

US Patent 5,071,417 issued December 10, 1991
"Laser Fusion of Biological Materials"

US Patent 5,042,980 issued August 27, 1991
"Optical Fiber Diffusion Tip for Uniform Illumination"

US Patent 5,009,655 issued April 23, 1991
"Hot Tip Device with Optical Diagnostic Capability"

US Patent 4,950,266 issued August 21, 1990
"Infrared Laser Catheter System"

US Patent 4,929,246 issued May 29, 1990
"Method for Closing and Sealing an Artery After Removing a Catheter"

US Patent 4,917,084 issued April 17, 1990
"Infrared Laser Catheter System"

US Patent 4,878,492 issued November 7, 1989
"Laser Balloon Catheter"

US Patent 4,852,567 issued August 1, 1989
"Laser Tipped Catheter"

US Patent 4,850,351 issued July 25, 1989
"Wire Guided Laser Catheter"

US Patent 4,817,601 issued April 4, 1989
"Catheter System for Controlled Removal by Radiant Energy of Biological Obstructions"

**Edward L. Sinofsky, Ph.D. Publications:**

"Interferometrically Measuring Phase Mismatch for 2nd Harmonic Generation"
Sinofsky E; Hopf F;
APPLIED OPTICS, 1985 V24, N14, P2206-2210.

"Safety Interlocking Laser Output Prior to Optical Fiber Burnback"
Sinofsky E; Roth L;
Proceedings of SPIE- The International Society for Optical Engineering V576,
OPTICAL FIBERS IN MEDICINE AND BIOLOGY, 1985 P51-54.

"Measurement of Argon Laser Beam Spreading Through Arterial Plaque"
Sinofsky E; Dumont M;
LASERS IN THE LIFE SCIENCES 1(2), 1986 P143-150.

"Calculated Temperature Distribution in a Cylindrical Tissue Volume Under Laser Irradiation Below the Vaporization Threshold,"
Sinofsky EL; Andrus WS
Proceedings of SPIE- The International Society for Optical Engineering V712,
LASERS IN MEDICINE, 1987, P78-83.

"Comparative Thermal Modeling of Er:YAG, Ho:YAG, and CO2 Laser Pulses for Tissue Vaporization;" Sinofsky E;
Proceedings of SPIE - The International Society for Optical Engineering V712,
LASERS IN MEDICINE, 1987, P188-192.

"Measurement of Laser Beam Spreading in Biological Tissue;" Sinofsky E; Dumont M;
Proceedings of SPIE - The International Society for Optical Engineering, V712,
LASERS IN MEDICINE, 1987, P58-62.

"Laser Balloon Angioplasty of Normal Dog Coronary Arteries Invivo;" Sinclair IN; Jenkins RD; James LM; Sinofsky EL; Wagner MS; Sandor T; Schoen FJ; Spears JR;
AUSTRALIAN AND NEW ZEALAND JOURNAL OF MEDICINE, 1988, V18, N3, P379.

"The Development of a Laser Balloon for the Treatment (Rx) of Biliary and Gastrointestinal (GI Obstruction;" Fleischer D; Cattau E; Sinofsky E; Newsome J; Lack E; Benjamin S;
GASTROINTESTINAL ENDOSCOPY, 1988, V34, N2, P210-211.

"Temperature Measurement Using Silica and Fluoride Based Optical Fibers for Biological Applications," Sinofsky E; Dumont M;
Proceedings of the SPIE - The International Society for Optical Engineering V907 LASER SURGERY; CHARACTERIZATION AND THERAPEUTICS 1988 P131-136.

"Plaque-Media Rewelding with Reversible Tissue Optical Property Changes During Repetitive CW Nd:YAG Laser Exposure;
Spears JR; James LM; Leonard BM; Sinclair IN; Jenkins RD; Motamedi M; Sinofsky EL;
LASERS IN SURGERY AND MEDICINE, 1988 8(5), P477-485.

"Temperature Measurement of Laser Heated Biological Tissue"
Dumont M; Madden M; Sinofsky E;
SPIE, LASERS IN MEDICINE IV; 1989, Los Angeles.

"Development of a Laser Balloon for the Treatment of Gastrointestinal Obstruction"
Fleisher D; Cattau E; Sinofsky E; Newsome J; Andriuk A; Benjamin S;
ENDOSCOPY, 1989, V21, N2, P80-85.

"Percutaneous Coronary Laser Balloon Angioplasty: Initial Results of a Multicenter Experience" Spears J; Reyes V; Wynne J; Fromm B; Sinofsky E; et al.
JACC, August 1990, V16, N2, P293-303.

"Heat Resistant Cylindrical Diffuser for Interstitial Laser Coagulation: Comparison With the Bare-Tip Fiber in a Porcine Liver Model;" Heisterkamp J; van Hillesgersberg R; Sinofsky E; Ijzermans J; LASERS IN SURGERY AND MEDICINE; 1997; 20:304-309.

"Infrared Techniques for Detecting Carbonization at Onset of Device Failure;" Farr N; Sinofsky E; SPIE Proceedings, February 1997, Volume 2970:507-512.

"High Power Diffusing Tip Fibers for Interstitial Photocoagulation;" Sinofsky E; Farr N; SPIE Proceedings, February 1997, Volume 2970:513-521.

"Interstitial Nd:YAG Laser Coagulation Using Simultaneous Multiple Fiber Application with an Optical Beamsplitter: The Importance of Mutual Fiber Distance;" Heisterkamp J; van Hillesgersberg R; Sinofsky E; Ijzermans J; SPIE Proceedings, February 1997, Volume 2970:522-525.

"Increasing Lesion Size in Interstitial Laser Coagulation: The Importance of Eliminating Hepatic Perfusion;" van Hillesgersberg R; Heisterkamp J; Sinofsky E; Mulder P; Ijzermans J; SPIE Proceedings, February 1997, Volume 2970:538-542.